

CLAIMS

We claim:

1. A system for preparing an autologous solid-fibrin web suitable for regenerating tissue in a living organism, the system comprising:
 - 5 a sealed primary container containing a separation medium and a low-density high-viscosity liquid, the separation medium being capable of separating red blood cells from plasma when the container contains blood and is centrifuged, the primary container having a first pressure;
 - 10 a sealed secondary container containing a calcium-coagulation activator, the secondary container having a second pressure that is less than the first pressure; and
 - 15 a transfer device comprising a cannula having a first end and a second end, the first and second ends being capable of puncturing the sealed primary and secondary containers in order to provide fluid communication between the first and second containers, the low-density high-viscosity liquid of the primary container being capable of blocking flow through the cannula upon entering therein.
2. The system of claim 1, wherein the separation medium is at least one of a gel, beads and a float device.
3. The system of claim 1, wherein the secondary container is evacuated.
4. The system of claim 1, wherein the calcium-coagulation activator is
20 selected from calcium chloride, calcium fluoride, calcium carbonate, calcium gluconate, calcium fumarate, calcium pyruvate and combinations thereof.
5. The system of claim 1, wherein the primary container further contains an anti-coagulant.
6. The system of claim 1, wherein the first and second ends are each covered
25 by an elastomeric sleeve, the elastomeric sleeve being retractable when the first or second ends puncture the primary or secondary sealed containers.

10053247.01502

7. A system for preparing an autologous solid-fibrin web capable of regenerating tissue in a living organism, the system comprising:

a sealed primary container having a first pressure, the primary container being capable of having blood drawn therein;

5 a sealed secondary container having a second pressure and containing a calcium-coagulation activator, the second pressure being less than the first pressure;

a transfer device including a cannula having a first end and a second end, the first and second ends being capable of puncturing the sealed containers, the transfer device being capable of transferring a portion of blood drawn in the primary container to the
10 second container by pressure differentiation; and

a centrifuge for concurrently centrifuging and coagulating the portion of blood transferred from the primary container to the secondary container through the transfer device and brought into contact with the calcium-coagulation activator in order to form a solid-fibrin web that is capable of regenerating tissue in a living organism.

15 8. The system of claim 7, wherein the transfer device further comprises a first sleeve covering the first end and a second sleeve covering the second end.

9. The system of claim 7, wherein the calcium-coagulation activator is selected from calcium chloride, calcium fluoride, calcium carbonate, calcium gluconate, calcium fumarate, calcium pyruvate and combinations thereof.

20 10. The system of claim 7, wherein the primary container contains a separation medium, a high-viscosity-low-density fluid and an anticoagulant.

11. The system of claim 10, wherein the separation medium is at least one of gel, beads and a float.

12. The system of claim 7, wherein the transfer device further comprises a
25 housing and the housing extends beyond the length of the cannula in order to protect a user's fingers from being pricked.

10053247.011502

13. A method of preparing a solid-fibrin web for regenerating body tissue in a living organism, the method comprising:

drawing blood from a patient into a primary container;

separating plasma from the blood in the primary container;

5 transferring plasma from the primary container to a secondary container containing a calcium-coagulation activator using a transfer device comprising a cannula having a first end and a second end in order to contact the plasma with the calcium-coagulation activator; and

10 concurrently coagulating and centrifuging the plasma and calcium-coagulation activator in the secondary container in order to form a solid-fibrin web therein, the solid-fibrin web being suitable for regenerating body tissue in a living organism.

14. The method of claim 13, wherein the primary and secondary containers are sealed to prevent contamination of contents therein, the primary container having a first pressure and the secondary container having a second pressure that is less than the first pressure.

15 15. The method of claim 14, whereby transferring plasma from the primary container to the secondary container is accomplished by penetrating the sealed primary container with an end of the cannula and penetrating the sealed secondary container with the other end, in no particular order, thereby allowing plasma to flow from the primary container to the secondary container.

16. The method of claim 13, whereby separating plasma from the blood in the primary container comprises providing the primary container with a separation medium, viscous liquid and an anticoagulant and centrifuging the primary container and contents thereof.

25 17. The method of claim 16, whereby centrifuging the primary container forms centrifuged contents therein, and the centrifuged contents form the following layers in order from a bottom of the primary container to a top of the container: blood, separation medium, plasma, viscous liquid, air and seal.

10053247.011502

18. The method of claim 17, further comprising inverting the primary container before inserting the transfer device therein such that the centrifuged contents in the primary container form the following layers in order in the inverted container: the seal, plasma, viscous liquid, air, separation medium and blood.

5 19. The method of claim 18, wherein one end of the cannula is inserted through the inverted sealed primary container and the other end is inserted into the sealed second container, in no particular order, in order to transfer the plasma from the primary container through the cannula, and wherein once the viscous liquid enters the cannula during transfer, the viscous liquid blocks communication between the primary and secondary
10 containers.

20. A system for preparing a solid-fibrin web suitable for regenerating tissue in a living organism, the system comprising:

a sealed primary collection device having an interior and containing a separation medium, the primary collection device being capable of having blood drawn into the
15 interior, the separation medium being capable of separating plasma from red blood cells when the primary collection device contains blood and is centrifuged; and

a reservoir having a chamber and a conduit in fluid communication therewith, the chamber having a calcium-coagulation activator therein, and the conduit being at least partially filled with a blocking medium to prevent the activator from flowing out of the
20 chamber under ambient conditions.

21. The system of claim 20, wherein the conduit is a cannula, and the cannula has an end capable of puncturing the sealed primary collection device.

22. The system of claim 21, wherein the end is covered by an elastomeric sleeve that is capable of retracting when the end punctures the sealed primary container.

23. The system of claim 20, wherein the blocking medium has a yield point such that it does not move when the system is centrifuged at about 900 to about 1500 xG, but that does move into the primary collection device when the cannula of the reservoir pierces the seal of the reservoir and the system is centrifuged at about 2300 to about 6000 xG.

24. The system of claim 20, wherein the calcium-coagulation activator is at least one of calcium chloride, calcium fluoride, calcium carbonate, calcium gluconate, calcium fumarate, calcium pyruvate and combinations thereof.

25. The system of claim 20, wherein the collection device and the reservoir are integral, and the conduit provides the only fluid communication between the interior of the collection device and the reservoir.

26. A method of preparing a solid-fibrin web capable of regenerating tissue in a living organism, the method comprising:

- drawing blood from a patient into a primary collection device having a seal;
- 10 providing a reservoir including a chamber and a conduit in fluid communication with the chamber, the chamber being at least partially filled a calcium-coagulation activator, the conduit being at least partially filled with a blocking medium to prevent the activator from flowing out of the chamber under ambient conditions;
- connecting the reservoir to the primary collection device such that the chamber, 15 conduit and collection device would be in fluid communication but for the blocking medium;
- centrifuging the primary collection device at a first rate, the first rate being sufficient to separate plasma from blood, yet not sufficient to move the blocking medium in the conduit into the primary collection device; and
- 20 centrifuging the primary collection device at a second rate, the second rate being sufficient to move at least a portion of the blocking medium from the conduit into the primary collection device, thereby allowing the calcium-coagulation activator to flow into the collection device and contact the plasma; and
- continuing to centrifuge the device at the second rate, thereby forming a solid- 25 fibrin web suitable for regenerating tissue in a living organism.

27. The method of claim 26, whereby centrifuging the primary collection device at the second rate is preformed for a sufficient time to concurrently centrifuge and coagulate the plasma and activator in order to form the fibrin web.

28. The method of claim 26, wherein the calcium coagulation activator is at least one of calcium chloride, calcium fluoride, calcium carbonate, calcium gluconate, calcium fumarate, calcium pyruvate and combinations thereof.

10053247 011502

29. The method of claim 26, wherein the conduit is a cannula having a sharp end, and wherein connecting the reservoir to the primary collection device is accomplished by puncturing the seal with the end of the cannula.

30. The method of claim 29, wherein the end of the cannula is covered by an elastomeric sleeve capable of being retracted when the end punctures the seal.

31. The system of claim 1, wherein the secondary container contains one or more of an antibiotic, an analgesic, a cancer therapeutic, a platelet-growth factor and a bone morphogenic protein.

32. The system of claim 7, wherein the secondary container contains one or more of an antibiotic, an analgesic, a cancer therapeutic, a platelet-growth factor and a bone morphogenic protein.

33. The system of claim 20, wherein the chamber contains one or more of an antibiotic, an analgesic, a cancer therapeutic, a platelet-growth factor and a bone morphogenic protein.

34. The method of claim 26, wherein the chamber contains one or more of an antibiotic, an analgesic, a cancer therapeutic, a platelet-growth factor and a bone morphogenic protein.

ADD
A1

10053247.011502